REMARKS

Please amend claims 1, 9, 24, 26, 27, 30 and 31. No new matter is added as a result of these amendments. Support for the amendments may be found at least on page 10, lines 4-14, in the examples and throughout the application as originally filed. Applicants have amended the claims in a manner which they believe addresses the Examiner's concerns and which places the claims in condition for allowance. For at least the above reasons, it is submitted that claims 1-7, 9-17, 24 and 26-32 continue to be in a condition for allowance.

Rejections Under 35 U.S.C. § 112 ¶2

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

On pages 3-4, section 9a-d, claims 1-7, 9-17, 24 and 26-32 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly containing subject matter which fails to particularly point out and distinctly claim the invention. Applicants have amended the claims to delete the following phrases "metabolically modifying", "including E. coli", "said substrate material" and "susceptibility to attack by bacteriophages". Applicants submit that their claims were definite prior to these amendments. They continue to be definite. Accordingly, the rejection is moot.

35 U.S.C. § 112 ¶ 1

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

On pages 4-8, section 10 claims 1-3, 6-7, 9-17, 24, 26-27 and 30-32 stand rejected under 35 U.S.C. §112 ¶ 1, as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Further, the Examiner states "the specification discloses only two representative species of the genus of recited bacterial cultures or modified lactic acid bacterium, i.e., a purine (Pur-) or a thymidine (*thy*A) auxotrophic bacterium". On pages 8-13, section 11 claims 1-7, 9-17, 24 and 26-32 stand rejected under 35 U.S.C. §112, ¶ 1 as allegedly failing to satisfy the enablement requirement because "while being enabling for a method of acidifying milk using a purine or pyrimidine auxotrophic bacterial culture , [the specification] does not reasonably provide enablement for a method of performing *any* modification of milk using *any* bacterial culture which is capable of being metabolically

active in said milk but is not capable of DNA replication, RNA transcription, or protein synthesis or *any* modified lactic acid bacterium ...". It was asserted that undue experimentation would be required to make the entire scope of the claimed invention. It was also stated that the application as filed does not provide written description or enablement for a method of performing *any* modification of milk using *any* bacterial culture which is capable of being metabolically active in said milk but is not capable of DNA replication, RNA transcription or protein synthesis. The Examiner states that he can only identify two species of the genus and that these fail to represent the entire genus of bacterial cultures. At least for the reasons below, Applicants respectfully traverse the rejection.

Initially, Applicants submit that their claims prior to the present amendment satisfied the written description requirements for all the reasons previously submitted. Nonetheless in the interest of expediting prosecution, Applicants have amended claim 1 from "*modifying*" milk to "fermenting" milk. Further, Applicants have amended claim 1 to recite the bacterial culture being one which "is metabolically active and thereby enabling an acidification of milk". As such, the specification contains a written description (and enablement) for a broader scope of the invention than now claimed. A person skilled in the art would know how to select a bacterial culture which falls within the full scope of the present claim 1. The specification provides further written description of bacterial strains which can be used in the invention, e.g., page 18, lines 21-28, a number of substrates, e.g., page 10, lines 29-page 11, line 3 and a number of mechanisms, which can be used to provide a suitable bacteria or bacterial cultures, e.g., page 8, line 7-page 9, line 25 which are discussed further below and in the accompanying declaration.

As described on page 6, lines 23-26 of the specification, the claimed invention is based on utilizing non-proliferating strains which are unable to grow in a specifically defined substrate material but which have retained their ability to being metabolically active and thus are capable of fermenting milk. Applicants claim methods of fermenting milk in the presence of non-proliferating strains where auxotrophic bacterial strains are used as examples of strains that have the properties of being incapable of DNA replication, RNA transcription or protein synthesis in milk but remaining metabolically active and thereby able to acidify milk. It is submitted that bacterial strains with such properties provide enabling disclosure as well as being adequately described in Applicants' specification as originally filed to satisfy 35 U.S.C. §112, ¶ 1 for the full scope of the claims. See for instance, MPEP 2163, page 2100-168 wherein it is stated that "the

written description requirement for a claimed genus may be satisfied ... by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties..."

The use of pur⁻ and *thy*A mutants are exemplary only as used in the specification for such non-proliferating bacterial strains which are useful in the claimed method. Thus, the specification discloses further examples of useful non-proliferating strains and how to provide them. For instance, on page 12, lines 11-17, the use of "resting cells" or "non-dividing cells" is disclosed. Such cells are incapable of mitose or meiose due to the deficiency of DNA, RNA or protein needed for the separation of the cells. Thus, the cells are capable of increasing size without mitose but are metabolically active because RNA and proteins are still synthesized. On page 12, lines 19-32 of the specification the use of "conditional mutants" is described which is a further example of useful non-proliferating bacterial strains. Such mutants are not capable, under predetermined conditions, e.g. pH, temperature, presence/absence of inducer substrates, to perform DNA replication, RNA transcription or protein synthesis.

In the enclosed Declaration of Dr. Thomas Janzen, the applicability of the teachings disclosed in the specification and of the claimed invention to other types of bacterial modification is shown and demonstrates another example of a useful non-proliferating bacterial strain.

In the Declaration it is demonstrated how a DNA polymerase mutant strain can be constructed by following the teachings of the specification. Such a strain could be constructed by coupling the DNA polymerase gene of a lactic acid bacteria to an inducible promoter in such a way that the DNA polymerase is expressed under specific growth conditions, but is not expressed during the growth in milk. The activity of the inducible promoter could be dependent on a specific salt concentration or a specific temperature which is present during the culture production of the strain, but not during the dairy fermentation.

Such a mutant with a partial or completely inactivated DNA polymerase falls within the scope of Applicants' claim 1 as such a mutant is not capable of DNA replication in milk but is capable of fermenting the milk as its RNA transcription is intact and it is submitted that such a mutant strain would have an acidification rate which is at least 10% of that of the bacterial strain when it is present in a medium where it is capable of DNA replication.

Dr. Janzen concluded in his Declaration that, "the disclosure of the specification of the present application is sufficient for me to construct different kinds of bacterial strains which are useful in the claimed method of fermenting milk and which are unaffected by the presence of bacteriophages in said milk". (Declaration, page signature). It is clear from Dr. Janzen's Declaration that he did not have to engage in an undue amount of experimentation to practice various aspects of the claimed invention without undue experimentation.

Applicants traverse this rejection as Applicants have provided a teaching which provides both written description and enablement to those skilled in the art to practice the entire scope of the claimed invention.

The rejection is respectfully traversed.

Conclusion

All claims are in condition for allowance, an indication of which is solicited. In the event any outstanding issues remain, Applicants would appreciate a telephone call to their undersigned counsel to resolve such issues in an expeditious and effective manner.

It is believed that no fees are due in connection with this Amendment. However, if any additional fees are determined to be due, the Director is hereby authorized to charge such fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS

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